DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region MD450N

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6008

WARNING LETTER

Certified Mail
Return Receipt Requested

File # 99-NWJ-17

March 11, 1999

Joseph G. Lotito
President
Lebanon Cheese Co.
Railroad Avenue
Lebanon, NJ 08833

Dear Mr. Lotito:

During an inspection at your firm located at the above address, our Investigators documented insanitary conditions in violation of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), whereby your products, ricotta and mozzarella cheese, were prepared, packed or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. Also, where indicated, the insanitary conditions are in violation of Current Good Manufacturing Practices in Manufacturing, Packing or Holding Human Food (Title 21, Code of Federal Regulations). In addition, the two products you manufacture, ricotta and mozzerella cheeses, are standardized in Title 21, Code of Federal Regulations.

The observations disclosed during the inspection include:

1. Failure to maintain documentation of certificates of analysis indicating the quality of the raw milk used in the manufacture of your cheese products *[21 CFR 110.80(a)(2)]*.

2. Failure to manufacture food products under such conditions and controls as are necessary to minimize the potential for growth of microorganisms, or for the contamination of food, including:

   - The use of an uncleaned and unsanitized brush to remove excess product from the finished product tins *[21 CFR 110.80(b)(1)]*.

- The use of water spray to remove excess product from the finished product containers prior to their closure without adequate protection of the product contained therein *[21 CFR 110.80(b)(5) & (13)].*

- The storage of finished product tins in standing water on worktable surfaces, in which the surfaces were unclean and encrusted with residue *[21 CFR 110.80(13)(iv)].*

- Personnel handling unclean surfaces, followed by the handling of food-contact surfaces, without washing and sanitizing gloves *[21 CFR 110.10(b)(3)].*

- Contact of product utensils with unclean surfaces, followed by their use without cleaning or sanitizing *[21 CFR 110.80(b)(7)].*

- Sanitizer solutions were not present in the manufacturing area where required and, where present, you failed to monitor the concentration of those solutions *[21 CFR 110.37(e)(1)].*

- Vessels used to store raw milk show evidence of milkstone residue, indicating inadequate cleaning *[21 CFR 110.80(b)(7)].*

- Personnel used improper hair restraints during manufacturing operations *[21 CFR 110.10(b)(6)].*

3. Inadequate facilities and accommodations to properly convey freestanding water from manufacturing and packaging areas *[21 CFR 110.37(b)(2)]* and provide adequate ventilation to minimize vapors producing condensate which may contaminate food *[21 CFR 110.20(b)(6)].*

4. Handwashing facilities are inadequate and/or inoperable *[21 CFR 110.37(b)].* The handwash sink in the production area was inoperable and soap/detergent was located 20 feet away from this sink.

5. Inadequate toilet facilities in that those facilities for men were unlighted *[21 CFR 110.37(d)].*

Many of the observations were previously noted in a May, 1997 FDA inspection and two New Jersey Department of Health inspections in March, 1996 and May, 1996. Those observations were not corrected despite assurances to the inspectors that they would be.

The above is not intended to be an all-inclusive list of violations. As a manufacturer of human food, you are responsible for assuring that your overall operation and the food products themselves are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction.

You should notify this office in writing within 15 working days' receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Kirk D. Sooter, Compliance Officer, at the address and telephone number above.

Sincerely yours,

Edward H Wilbanks for
Douglas I. Ellsworth
District Director